DETAILED ACTION

This Office action is in response to the communication filed 1-29-10.

Claims 1-28 are pending in the instant application. Claims17-28 are withdrawn as being drawn to a non-elected invention. Claims 1-16 have been examined on their merits as set forth below.

Response to Arguments and Amendments

Withdrawn Rejections

Any rejections not repeated in this Office action are hereby withdrawn.

New Rejections

Applicant's arguments with respect to claims 1-16 have been considered but are moot in view of the new ground(s) of rejection set forth below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kanda et al (USPN 7,393,583) in view of Vickers et al (J. Biol. Chem., Vol. 278, No. 9, pages 7108-7118 (Feb. 2003) and Tuschl et al (WO 02/44321).

Kanda et al (USPN 7,393,583) teach a process for producing antibodies comprising using a cell which has been transfected with siRNA that specifically target and inhibit the expression of α1,6-fucosyltransferase encoded by SEQ ID NO. 1, or having at least 80% homology with the target gene of SEQ ID NO. 1, which encodes SEQ ID NO. 5, and which cell is an animal cell (CHO) and is resistant to *lens culinaris* lectin, and which cell is a transformant into which a recombinant gene encoding an antibody has been introduced, which antibodies are optionally humanized IgG antibodies and have higher antibody dependent cell mediated cytotoxic activity compared to cells that have not been transformed with an siRNA that inhibits the expression of α1,6-fucosyltransferase (see entire document, esp. col. 1-20, claims 1, 2, 6; SEQ ID NO. 2 encoding the instantly claimed target α1,6-fucosyltransferase).

Kanda does not teach the siRNA molecule of SEQ ID NO. 11.

Vickers et al (J. Biol. Chem., Vol. 278, No. 9, pages 7108-7118 (Feb. 2003) teach the design and assessment of siRNA molecules to inhibit the expression of a known target gene (see entire text, esp. Table 1 on p. 7111, Fig. 2 on p. 7112, Table 2 on p. 7113).

Tuschl et al (WO 02/44321) teach the design, assessment and optimization of siRNA molecules for inhibiting the expression of a known target gene (see entire document, esp. pages 1-4, Figs. 7-19).

It would have been obvious to design, assess and optimize siRNA for their ability to inhibit the expression of a known target gene because Kanda, Vickers and Tuschl all teach the routine experimentation involved in designing and testing the ability of siRNA to inhibit the expression of a corresponding gene of known sequence. One would have been motivated to inhibit the target gene α1,6-fucosyltransferase using such siRNA molecules because the target gene was previously taught by Kanda, as well as the ability to inhibit its expression in an appropriate host cell, such as CHO, for enhancing production of recombinant antibodies with the desired characteristic of modulated antibody dependent mediated cell mediated cytotoxicity because Kanda taught the instantly claimed process of inhibiting α1,6-fucosyltransferase activity in host cells, including CHO host cells in order to achieve production of recombinant antibodies whose sugar chains have less fucose termini bound to the N-acetylglucosamine reducing end on their complex type N-glycoside linked sugar chains in the Fc region, thereby imparting the characteristics that are instantly claimed. It would have been obvious to design and test an siRNA comprising SEQ ID NO. 11, or sharing at least

80% homology with this siRNA because Kanda taught the polynucleotide sequence of the target fucosyl transferase gene, as well as teaching various siRNA molecules that have the ability to inhibit the transferase expression, and Tuschl and Vickers taught the routine experimentation for designing siRNA directed against a target gene of known sequence. One of skill in the art would have reasonably expected that an siRNA having at least 80% homology with the target gene, including the siRNA comprising SEQ ID NO. 11, would inhibit the expression of α1,6-fucosyltransferase, thereby imparting the desired characteristics onto the host cells, and the recombinant antibody molecules, as instantly claimed.

For these reasons, the instant invention would have been obvious to one of skill at the time of filing.

Conclusion

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. ' 1.6(d)). The official fax telephone number for the Group is **571-273-8300**. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is **(571) 272-0765.** If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fereydoun Sajjadi, can be reached on (571) 272-3311. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jane Zara
4-16-10

/Jane Zara/

Primary Examiner, Art Unit 1635